

designing superantigen toxins with low binding affinities. These residues can include Y94 of SEB . . . .Furthermore . . . side chains of amino acids within 5 residues of the position represented by N23. . . ., N60 . . . , Y91. . . , and D210 of SEB. . . can be altered when designing superantigen toxins with low binding affinities. (Emphasis added)

In addition, claim 110 is canceled without prejudice or disclaimer. New claim 111 is added to replace claim 110 and address the Examiner's concerns under 35 U.S.C. §112, second paragraph.

New claim 112 is added, which also finds support on pages 19-21 of the specification. New claim 113 is added, which is supported by the description in Example 9 of vaccine B899445.

No new matter is introduced via these amendments to the claims, or by the new claims, and entry and consideration are respectfully requested.

In the December 12 Office Action, the Examiner on page 2 stated:

The request filed on 7/2/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/882,431 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed 7/2/02 has been entered.

We note that some of the dates referred to here are incorrect. In particular, the request for a CPA was filed on April 10, 2002, with a Preliminary Amendment, and an Amendment was subsequently filed (responsive to an Office Action) on September 26, 2002.

The Examiner indicated that claims 4-6, 12-14 and 21-23 are allowable, and that claims 37-39 (among others) are objected to as depending upon rejected claims. However, claims 37, 38 and 39 depend from claims 21, 22 and 23, respectively, which are allowed claims. Thus, we assume that the inclusion of claims 37-39 with the other objected-to claims was a typographical error.

The Examiner rejected claims 1, 18, 43, 44, 53, 62 and 110 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention at the time the application was filed. We have canceled claim 110 above, so to the extent this rejection applies to this claim it is now moot. However,

with respect to the other rejected claims, we have amended independent claim 1 to more specifically track the language in the specification regarding the amino acid alterations. New claims 112 and 113 also recite more specific combinations of altered amino acids. As noted above, these claims find specific support in the specification on pages 19-21 and in Example 9, and therefore meet the criteria of §112, first paragraph. Reconsideration is requested.

Claim 110 also stands rejected under 35 U.S.C. §112, second paragraph. We have canceled this claim without prejudice or disclaimer, and replaced it with new claim 111 which recites the construct pETB2360210. This new claim is clearly described in the specification, and withdrawal of this rejection is believed to be in order.

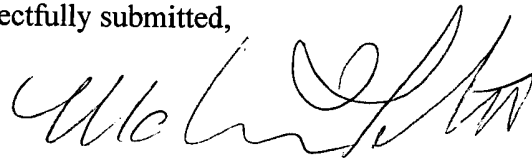
In summary, it is submitted that the language of all the pending claims is fully supported by the disclosure as originally filed, and withdrawal of this rejection is believed to be in order. All of the Examiner's outstanding rejections and objections have been addressed, and the application is believed to be in allowable form. Notice to that effect is earnestly solicited. No amendment made was related to the statutory requirements of patentability unless expressly stated herein, and no amendment made was for the purpose of narrowing the scope of any claim unless we argued above that such amendment was made to distinguish over a particular reference or combination of references.

App. of Ulrich et al.  
Ser. No. 08/882,431

If the Examiner has any questions or would like to make suggestions as to claim language, she is encouraged to contact Marlana K. Titus at (301) 762-8214.

Respectfully submitted,

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MARKED-UP VERSION OF AMENDED CLAIMS

1. (Five times amended) An isolated and purified superantigen toxin DNA fragment encoding Staphylococcal enterotoxin B (SEB) in which at least [two] one amino [acids] acid selected from the group [of amino acid positions of SEB consisting of 18-28, 40-50, 55-65, 62-72, 84-94, 86-96, 89-99, 110-120 and 205-215] consisting of amino acid positions 40-50, 62-67, 84-89 and 110-120 of SEB, and at least one amino acid of amino acid positions 18-28, 55-65, 86-96, 89-99, and 205-215 of SEB have been altered such that binding of said encoded SEB to the MHC class II receptor and T cell antigen receptor is altered.